JUL - 7 2000

K001251

SECTION E 510(k) SUMMARY

510(k) Number: _____

Trade Name: *Sniper™* Hydrophilic Nitinol Guide Wire

Common Name: Guide Wire

Classification Name: Catheter Guide Wire (per CFR 21 Part 870.1330, 74 DQX)

Product Code: DQX

Classification: Class II

Submitted by:
Nipro Medical Corporation
3150 N.W. 107th Ave.
Miami, FL 33172
Phone: 305-599-7174
Fax: 305-599-8454

Contact person: Cary Goldsmith, Product Manager

Date prepared: 4-14-2000

Legally marketed devices to which equivalence is claimed:

Terumo Radifocus Glidewire, K863138

Description of Device:

The *Sniper™* Hydrophilic Guide Wire is constructed from a super elastic, Nitinol core wire. A plastic cladding is applied over the Nitinol core, with a hydrophilic coating covering the plastic cladding. The polymer cladding is impregnated with a radiopacive agent for enhanced contrast under fluoroscopy.

Scientific concepts that form the basis for the device:

This guide wire has a core made from Nitinol, a metal that has a high resistance to kinking. The Nitinol core is coated with a polymer of low enough durometer to not inhibit the super-elastic properties of Nitinol. The plastic cladding is coated with a

durable hydrophilic coating, to provide a virtually frictionless surface when wet. The radiopacive agent that is impregnated in the polymer cladding provides enhanced radiopacity when imaged under fluoroscopy.

Intended Use of Device:

Sniper™ Hydrophilic Nitinol guide wires are designed for use in angiographic procedures below the head and neck, to introduce/position catheters and interventional devices within the vasculature for radiological and urological applications.

Comparison of Technological Characteristics to legally marketed device:

The *Sniper*™ Hydrophilic guide wire is being compared to the Terumo Radifocus Glidewire.

The predicate device has a Nitinol core, as does the *Sniper*™ Hydrophilic guide wires, in which both are totally covered by a polymer cladding. The polyurethane cladding in both the *Sniper*™ Hydrophilic guide wire and the Glidewire (analysis in Technical Report, 900-TR-532) are impregnated throughout with a radiopacifier for enhanced visualization during fluoroscopy. Both the Glidewire and the *Sniper*™ wire utilize a radiopacifier to enhance fluoroscopic visualization. The polymer cladding in both devices is coated with a hydrophilic coating. Both the Glidewire and Sniper retain their lubricity over multiple uses and thus possess the durability for repeated usage during a procedure. Both wires resist kinking and retain the original conformation even when placed in severe tortuousity. The differences stated do not affect the safety and effectiveness of the device. The *Sniper*™ Hydrophilic guide wire has been completely tested for biocompatibility according to the FDA's General Program Memorandum #G95-1, Use of International Standard ISO-10993, "Biological Evaluation of Medical Devices, Part 1: Evaluation and Testing, May 1, 1995.

Performance Data:

Testing was conducted in accordance with the FDA's Coronary and Cerebrovasculature Guidewire Guidance (Jan. 1995) and the ISO Standard 11070, Sterile single-use intravascular catheter introducers (5-1-98). The following tests demonstrated substantial equivalence:

- Lubricity
- Coating Adherence
- Torque Strength
- Torqueablility
- Tip Softness
- Tip Flexibility
- Tensile Strength
- Fracture Test
- Kink Resistance

- Radiodectibility
- Catheter Compatibility

Test results demonstrate that the *Sniper™* Hydrophilic Guide wire is substantially equivalent to the Terumo Radifocus Guidewire.

Packaging and Sterilization Information

Nipro Medical Industries Ltd. shall package the guide wire (enclosed in the dispenser) along with a plastic torque device (made by Maxxim Medical) in a single put-up pouch and sterilize. The pouch may be packaged as 5 pouches in a shelf carton 5-pack, as the typical packaging configuration.

Maxxim Medical, the initial distributor, shall package the guide wire (enclosed in the dispenser) in PVC or styrene trays, packs or kits with Tyvek lidstock and sterilize. The guide wire may be distributed from Nipro Medical Corporation to Maxxim Medical in the guide wire dispenser, bulk-nonsterile and that customer is responsible for validation of the packaging and sterilization.

Sterilization at both Maxxim Medical and Nipro Medical Industries Ltd. is by a validated ethylene oxide sterilization (EtO) method that is referenced in ANSI/AAMI/ISO 11135-1994 "MEDICAL DEVICES- Revalidation and Routine Control of Ethylene Oxide Sterilization."

CONCLUSIONS:

Nipro Medical concludes that the *Sniper™* Hydrophilic guide wires is substantially equivalent to the Terumo Radifocus Glidewire:

1) functionally and
2) with regards to safety and effectiveness

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL - 7 2000

Nipro Medical Corporation
c/o Jack Frautschi, Ph.D.
Maxxim Medical
1445 Flat Greek Road
Athens, TX 75751

Re: K001251
Trade Name: *Sniper*™ Hydrophilic Guide Wire
Regulatory Class: II (two)
Product Code: 74 DQX
Dated: April 13, 2000
Received: April 19, 2000

Dear Dr. Frautschi:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. However, you are responsible to determine that the medical devices you use as components in the kit have either been determined as substantially equivalent under the premarket notification process (Section 510(k) of the act), or were legally on the market prior to May 28, 1976, the enactment date of the Medical Device Amendments. Please note: If you purchase your device components in bulk (i.e., unfinished) and further process (e.g., sterilize) you must submit a new 510(k) before including these components in your kit. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, and labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval) it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality

System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, FDA will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, the Food and Drug Administration (FDA) may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal Laws or Regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market. If you desire specific advice for your device on the labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4586. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll free number (800) 638-2041 or (301) 443-6597, or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

James E. Dillard III
Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

SECTION D INDICATIONS FOR USE

Device Name: *Sniper*™ Hydrophilic Nitinol Guide Wire

Indications for Use:

Sniper™ Hydrophilic Nitinol guide wires are designed for use in angiographic procedures below the head and neck, to introduce/position catheters and interventional devices within the vasculature for radiological and urological applications.

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(Division Sign-Off)
Division of Cardiovascular, Respiratory, and Neurological Devices

510(k) Number